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## **Xact<sup>®</sup> Rapid Exchange Carotid Stent System 5.7Fr (1.9mm)**

### **Instructions for Use**

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Limited to use by physicians experienced in carotid stenting and who have received appropriate training in the use of the Xact<sup>®</sup> Carotid Stent System. The Xact<sup>®</sup> Carotid Stent System is indicated for use with the Emboshield<sup>®</sup> Embolic Protection System.



Sterilised by Ethylene Oxide



Single use only



Do not use opened or damaged  
goods

Manufactured for Abbott Vascular Devices, Abbott Laboratories by MedNova Ltd., IDA Enterprise Park,  
Tuam Rd., Galway, Ireland  
Distributed in the US by Abbott Laboratories Inc.  
Customer Service: 1(800) 222-6883

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# XACT<sup>®</sup> Carotid Stent System

## Information for Prescribers

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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## 1.0 DEVICE DESCRIPTION

The Xact® Carotid Stent System is comprised of a delivery system and a self-expanding stent. The delivery system is a rapid exchange (RX) system designed to deliver the self-expanding stent to the carotid vasculature.

The self-expanding stent is cut from Nitinol tube into a flexible tubular prosthesis. Upon deployment of the stent into the carotid vasculature via the delivery system, the stent should appose the vessel wall and apply an outward pressure to establish patency. The Xact® stent is available in both tapered and straight configurations, with diameters ranging from 6mm through 10mm. Stent lengths range from 20mm through 40mm. For more details, see the stent size matrix in **Table 1** of this document.

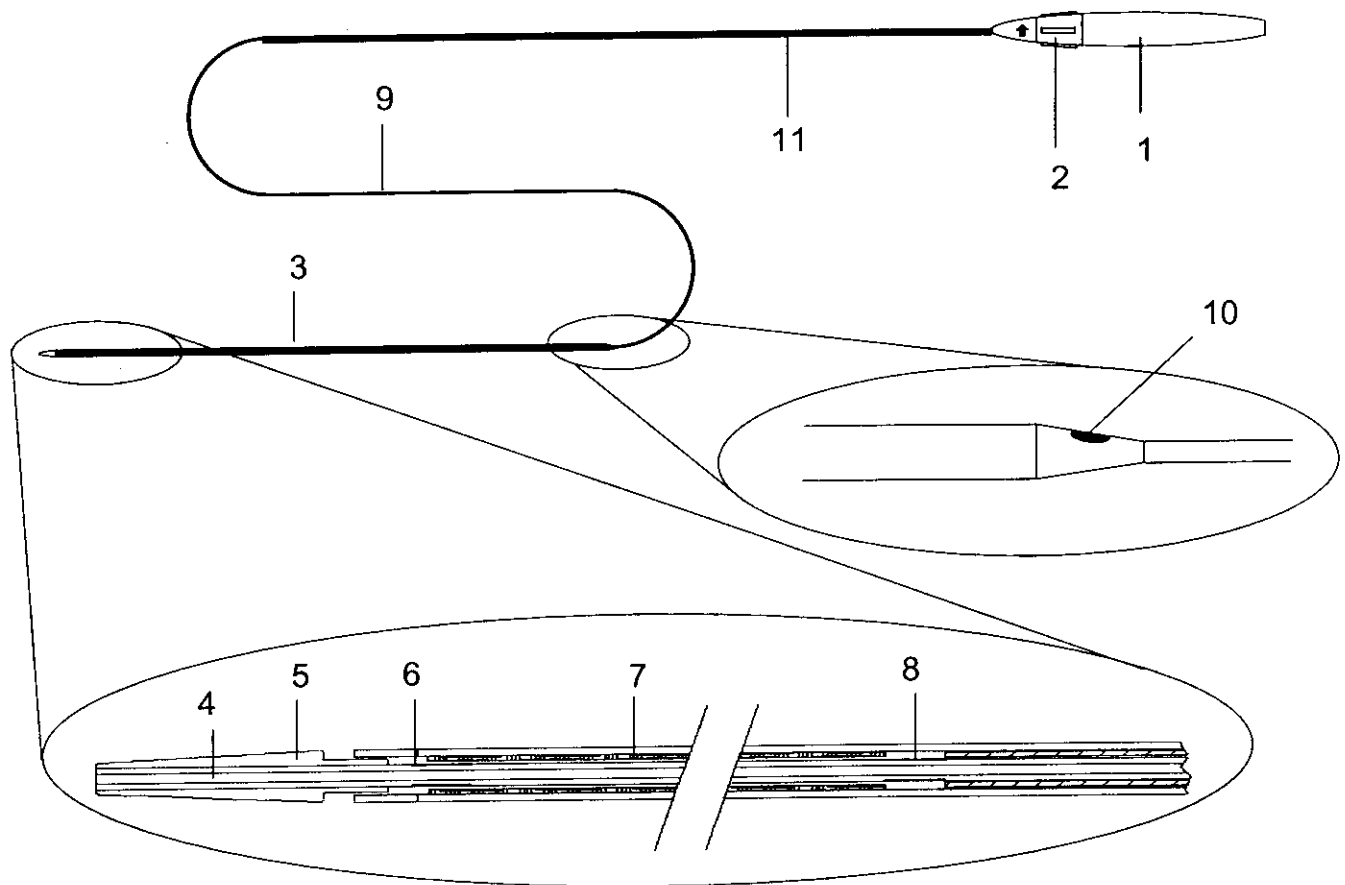


Figure 1: Xact® RX Carotid Stent System

### Delivery System

1. Handle
2. Deployment Actuator
3. Distal Outer Sheath
4. Guidewire Lumen
5. Tip

6. Radiopaque Distal Marker
7. Xact® Stent
8. Radiopaque Proximal Marker
9. Catheter Shaft
10. Guide Wire Exit Port
11. Stabilizer

The delivery system has an outer diameter (OD) of 5.7Fr and is compatible with 8F guiding catheter or a 6F sheath - with a 0.088" inner diameter or greater. The delivery system has a working length of 136cm. See Figure 1 for a graphical depiction of the Xact® Stent System. The delivery system is comprised of a tip (5), distal outer sheath (3), catheter shaft (9), and stabilizer (11). The distal outer sheath houses the crimped Xact® stent (7). At the proximal end of the distal outer sheath is the RX BareWire™ guide wire exit port (10). The proximal portion of the shaft and stabilizer connect the delivery system to the handle (1). The stabilizer (11) works with the hemostasis valve on the guiding catheter/sheath to help improve stent placement accuracy during deployment.

The inner system assembly consists of a tip (5) installed over a 0.014" RX BareWire™ guide wire compatible guide wire lumen (4). The guide wire lumen (4) is flushed via the tip (5) using the flushing tip. For more detailed instructions on device flushing, see the section entitled Delivery System Preparation in this document. The crimped Xact® stent is constrained between the guide wire lumen (4) and the distal outer sheath (3). There are radiopaque marker bands on the delivery system located at the proximal (8) and distal (6) ends of the stent. Prior to deployment, these radiopaque markers are used as guides to position the stent.

Deployment of the Xact® stent is achieved by grasping the handle (1) and rotating the deployment actuator (2) in a clockwise direction. See the section entitled Stent Deployment in this document for detailed instructions on deploying the stent.

### Tapered Stent

This stent is designed to fit tapered carotid anatomy, especially lesions involving the carotid bifurcation (Figure 2).

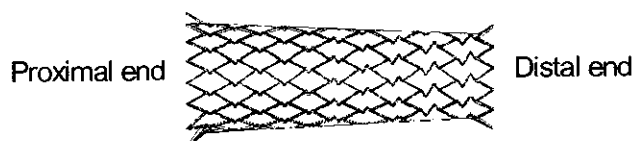


Figure 2: Tapered Stent

### Straight Stent

This stent is designed to be used within non-tapered carotid anatomy and lesions not involving the bifurcation (Figure 3).

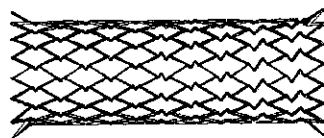


Figure 3: Straight Stent

Table 1: Device Range

Catalogue No.	Stent Length	Configuration	Unconstrained Stent Diameter
82095-01	20 mm	Straight	7 mm
82093-01	20 mm	Straight	8 mm
82089-01	20 mm	Straight	9 mm
82099-01	20 mm	Straight	10 mm
82094-01	30 mm	Straight	7 mm

Catalogue No.	Stent Length	Configuration	Unconstrained Stent Diameter
82092-01	30 mm	Straight	8 mm
82088-01	30 mm	Straight	9 mm
82098-01	30 mm	Straight	10 mm
82091-01	30 mm	Tapered	8-6 mm
82087-01	30 mm	Tapered	9-7 mm
82097-01	30 mm	Tapered	10-8 mm
82090-01	40 mm	Tapered	8-6 mm
82086-01	40 mm	Tapered	9-7 mm
82096-01	40 mm	Tapered	10-8 mm

## 2.0 INDICATIONS

The Xact® Carotid Stent System ((Xact®), used in conjunction with the Abbott Vascular Devices embolic protection system is indicated for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined below:

Patients with carotid artery stenosis ( $\geq 50\%$  for symptomatic patients by ultrasound or angiography or  $\geq 80\%$  for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery **AND**

Patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.

## 3.0 CONTRAINDICATIONS

Contraindications associated with angioplasty must be considered when using the Xact® Carotid Stent System. These include, but are not limited to:

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the Guiding Catheter/ Introducer Sheath RX BareWire™, Emboshield Delivery Catheter, Filtration Element, and/or Retrieval Catheter.
- Patients with a known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.

## 4.0 WARNINGS

**Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.**

### 4.1 GENERAL

Refer to instructions supplied with all interventional devices to be used with the Xact® Carotid Stent System for their intended uses, contraindications, and potential complications.

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The safety and efficacy of the Xact® Carotid Stent System has not been demonstrated with embolic protection systems other than the Emboshield® Embolic Protection System.

The long-term performance (> 1 year) of the Xact® Carotid Stent System has not been established.

As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.

The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

When multiple stents are required, stent materials should be of similar composition.

The safety and effectiveness of the Xact® Carotid Stent System has NOT yet been established in patients with the characteristics noted below.

- Low to moderate risk for adverse events from carotid endarterectomy.
- Previously placed stent in target artery.
- Total occlusion of target lesion.
- Angiographically visible thrombus.
- Carotid string sign (a tiny, long segment of contrast in the true lumen of the artery).
- Vessel anatomy precluding the use of the stent system or appropriate positioning of the embolic protection system.
- Presence of carotid artery dissection prior to initiation of the procedure.
- Evidence of a stroke within the previous 30 days.
- History of ipsilateral stroke with fluctuating neurologic symptoms within 1 year.
- History of intracranial hemorrhage within the past 3 months.
- Any condition that precluded proper angiographic assessment or made percutaneous arterial access unsafe, (e.g. morbid obesity, sustained systolic blood pressure >180 mmHg).
- Contraindication to aspirin, or to clopidogrel AND ticlopidine, or stent material.
- History or current indication of bleeding diathesis or coagulopathy including thrombocytopenia or an inability to receive heparin in amounts sufficient to maintain an activated clot time at > 250 seconds.
- Hemoglobin (Hgb) < 8gm/dl (unless on dialysis), platelet count < 50,000, INR > 1.5 (irreversible), or heparin-associated thrombocytopenia.
- Known cardiac sources of emboli.
- Atherosclerotic disease involving adjoining vessels precluding safe placement of the guiding catheter or sheath.
- Other abnormal angiographic findings that indicated the patient was at risk of a stroke due to a problem other than that of the target lesion, such as: ipsilateral arterial stenosis greater in severity than the target lesion, cerebral aneurysm, or arteriovenous malformation of the cerebral vasculature.
- Severe dementia.
- Life threatening allergy to contrast media that could not be treated.
- Pregnant patients or patients under the age of 18.
- Patients in whom femoral access is not possible.
- Patients with aneurysmal dilation immediately proximal or distal to the lesion.

The safety and effectiveness of concurrent treatment of lesions in patients with bilateral carotid artery disease have not been established.

## 4.2 SPECIFIC

The device is intended for single use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of cross contamination. Do not use if packaging is damaged.

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Do not use the product after the Use by Date specified on the label.

Store in a cool, dry area. Do not expose to organic solvents or ionizing radiation.

The clinician should be familiar with and experienced in standard techniques of Rapid Exchange percutaneous transluminal angioplasty and stenting and be knowledgeable of the current medical literature concerning the complications of such procedures.

Overstretching of the artery may result in rupture and life-threatening bleeding.

Appropriate anti-platelet, anticoagulant and, if necessary, vasodilator therapy must be used during the procedure. Anticoagulant therapy sufficient to maintain an Activated Clotting Time of at least 250 seconds for the duration of the procedure is recommended.

Maintain a snug seal between the device and the hemostasis Tuohy/Borst valve during insertion. Failure to observe this may result in air being drawn into the access device through the hemostasis/Tuohy Borst valve. Device insertion should be performed slowly to minimize the risk of air entrainment.

During the insertion of Rapid Exchange catheters through guide catheters or sheaths careful handling is required to ensure that air is not drawn into the access device. It is therefore recommended that flushing of contrast media (or other fluids) is performed before or after insertion of the catheter, but not while the catheter is within the access device.

Do not advance any component of the Xact<sup>®</sup> Stent Delivery System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

Perform all exchanges slowly to prevent air embolism or trauma to the artery.

Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).

The stent may cause thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

If a filter element embolic protection system is used, allow for and maintain adequate distance between the filter and the stent delivery system or deployed stent to avoid potential entanglement.

Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods (use of additional wire, snares, and/or forceps) may result in additional trauma to the carotid vasculature and/or the vascular access site. Complications may include death, stroke, bleeding, hematoma or pseudoaneurysm.

## 5.0 PRECAUTIONS

Carefully inspect device components prior to use to verify that they have not been damaged and that the size, shape and condition are suitable for the procedure for which they are to be used. A device or access device which is kinked or damaged in any way should not be used. If pouch is damaged do not use.

Confirm the compatibility of the Xact<sup>®</sup> Stent Delivery System with the interventional devices before actual use.

Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with sterile isotonic Heparinized saline prior to use.

Do not remove the stent from its delivery system as removal may damage the stent. The stent and delivery system are intended to be used in tandem. If removed, the stent cannot be put back on the delivery system.

The delivery system should not be used in conjunction with other stents.

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To reduce the potential for the liberation of emboli during lesion crossing, the device should be carefully manipulated and not advanced against resistance.

During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. The stent delivery system should not contact the Filtration Element.

Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

The device must only be flushed using the 3-ml syringe and flushing tip provided.

The outside diameter of the Outer Sheath is 5.7Fr. An appropriate sized sheath/guiding catheter should be selected based on this diameter.

Do not use a prepared Xact<sup>®</sup> Carotid Stent System if the stent is not fully constrained within the Delivery System.

Do not use if the stent is partially deployed.

If, after preparation, a gap between the catheter tip and the outer sheath exists, rotate the Deployment Actuator in an anti-clockwise direction until the gap is closed.

Advancement and deployment of the Xact<sup>®</sup> Carotid Stent System should only be performed under fluoroscopic observation.

Do not advance any component, or section thereof, of the Xact<sup>®</sup> Carotid Stent System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

Do not attempt to reposition the Delivery System once the stent has made contact with the vessel wall.

Do not torque the Xact<sup>®</sup> Carotid Stent System.

If more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion.

If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum.

## **5.1 MRI INFORMATION**

The Xact<sup>®</sup> Stent was determined to be MR-safe.

Magnetic resonance imaging (MRI) procedures must be performed according to the following guidelines:

A patient with the Xact<sup>®</sup> Stent may safely undergo an MRI procedure using an MR system with a static magnetic field of 3-Tesla or less. The Xact<sup>®</sup> Stent exhibits minor magnetic field interactions with respect to translational attraction (2-degrees deflection, tested at a maximum spatial gradient, 720 gauss/cm) and showed no torque during exposure to a 3-Tesla MR system. Therefore, there is no additional risk to a patient with the Xact<sup>®</sup> Stent with respect to movement, dislodgment, or migration using an MR system with a static magnetic field of 3-Tesla or less.

According to in vitro testing, an MRI procedure performed at a whole body averaged specific absorption rate (SAR) of 3.0-W/kg for 15 minutes at 3-Tesla in a patient with the Xact<sup>®</sup> Stent will produce a maximum temperature increase of 0.6°C. This amount of heating is considered to be physiologically inconsequential and will not impose an additional risk to the patient undergoing an MR procedure.

## **6.0 ADVERSE EVENTS**

### **6.1 OBSERVED ADVERSE EVENTS**

The SECURITY Registry Study was a prospective, multi-center, non-randomized study performed to demonstrate the safety and effectiveness of the Emboshield<sup>®</sup> Embolic Protection System and Xact<sup>®</sup> Carotid



Stent System in treating carotid stenosis in patients at high risk ( $\geq 50\%$  for symptomatic patients by ultrasound or angiography or  $\geq 80\%$  for asymptomatic patients by ultrasound or angiography) for carotid endarterectomy. High-risk patients were defined as having an anatomical risk factor(s) and/or a co-morbidity risk factor(s). A total of three hundred and five (305) patients were enrolled at 30 sites in the United States and Australia.

Non-stroke neurological includes events such as visual/speech disturbances, confusion, seizure, weakness, and TIA.

TLR is defined as any repeat invasive procedure, including angioplasty, stenting endarterectomy, or thrombolysis, performed to open or increase the luminal diameter inside or within 10 mm of the previously treated lesion. To be considered clinically indicated, the patient must be symptomatic with  $> 50\%$  stenosis or asymptomatic with  $> 80\%$  stenosis.

Adverse events are categorized by body system and are defined as follows:

- Access site complications include events such as bruising, hematoma, and bleeding.
- Vascular includes events such as peripheral vascular disease and deep vein thrombosis.
- Hemodynamic includes events such as hypo- and hypertension, syncope, and dizziness.
- Bleeding includes events such as non-access site bleeding, anemia up to 30 days, and Gastrointestinal (GI) bleeds up to 30 days.
- Blood dyscrasia includes events such as anemia later than 30 days, and thrombocytopenia.
- Respiratory includes events such as pneumonia, embolism, chronic obstructive pulmonary disease (COPD), and respiratory arrest.
- GI includes events such as nausea, ulcers and GI bleeds later than 30 days.
- Genitourinary includes events such as urinary tract infection, and prostatic hyperplasia.
- Infection includes events such as abscess, sepsis, and groin infection.
- Metabolic includes events such as electrolyte imbalance, diabetes Mellitus, and renal failure.
- Musculoskeletal includes events such as pain, fractures, and joint replacements.

The numbers and types of adverse events observed were anticipated given the high co-morbid state of these patients.

Table 2 presents the adverse events that were reported within the first 30 days following the procedure for registry patients enrolled in the SECURITY Registry Trial. Table 3 presents the adverse events that were reported within the first year following the procedure for registry patients enrolled in the SECURITY Registry Trial. Table 4 presents the cause of any patient deaths throughout the study.

**Table 2: Serious Adverse Events Summary, Up to 30 Days**

Events	<b><math>\leq 30</math> days SECURITY (N=305)</b>	
	<b>n</b>	<b>%</b>
All Death, Stroke and MI	26	8.52 %
Death	3	0.98 %
Stroke-Related	3	0.98 %
Not Stroke-Related	0	0 %
All Strokes	21	6.89 %
Major	8	2.62 %
Ipsilateral Stroke	7	2.30 %
Non-ipsilateral Stroke	1 <sup>1</sup>	0.33 %
Minor	13	4.26 %
Ipsilateral Stroke	12	3.93 %
Non-ipsilateral Stroke	1 <sup>2</sup>	0.33 %
Non-Stroke Neurological	25	8.20 %
Restenosis ( $\geq 50\%$ stenosis as measured by ultrasound)	7	2.29 %

<sup>1</sup> Stroke adjudicated as contralateral

<sup>2</sup> Stroke adjudicated as bilateral

Events	≤ 30 days SECURITY (N=305)	
	n	%
Target Lesion Revascularization (TLR), Clinically Indicated	0	0%
Cardiac	15	4.92 %
MI	2	0.66 %
Arrhythmia	4	1.31 %
Angina	4	1.31 %
Congestive Heart Failure (CHF)	3	0.98 %
Coronary Artery Disease (CAD)	2	0.66 %
Procedural Complication	109	35.74 %
Hypotension	86	28.20 %
Arrhythmia	7	2.30 %
Vasospasm	3	0.98 %
Dissection	10	3.28 %
In-stent Thrombosis	1	0.33 %
Emergent CEA	1	0.33 %
Emergent Intervention -other	1	0.33 %
Access Site Complication		
Requiring Repair / Transfusion	8	2.62 %
Vascular	3	0.98 %
Hemodynamic	11 <sup>3</sup>	3.61 %
Bleeding	6	1.97 %
Requiring transfusion	1	0.33 %
GI Bleeding	5	1.64 %
Blood Dyscrasia	2	0.66 %
Respiratory	5	1.64 %
Gastrointestinal	18	5.90 %
Genitourinary	3	0.98 %
Infection	2	0.66 %
Metabolic	11	3.61 %
Musculoskeletal	32	10.49 %
Miscellaneous <sup>4</sup>	1	0.33 %

Table 3: Serious Adverse Events Summary Up to 365 Days

Events	31-365 days SECURITY (N=302)		0-365 days SECURITY (N=305)	
	n	%	n	%
Death	26	8.6	29	9.5
Stroke-Related	3	1.0	6	2.0
Not Stroke-Related	23	7.6	23	7.5
Unknown	0	0.0	0	0
Ipsilateral Stroke	5	1.7	24	7.9
Major	4	1.3	11	3.6
Minor	1	0.3	13	4.3
Non-ipsilateral Stroke	1	0.3	2	0.7
Non-Stroke Neurological	18	6.0	43	14.1
Restenosis (≥ 50% stenosis as measured by ultrasound)	14	4.6	20	6.6
Target Lesion Revascularization (TLR), Clinically Indicated	2	0.7	2	0.7

<sup>3</sup> Includes hypotension and hypertension not associated with the procedure.

<sup>4</sup> Aortic Aneurysm Repair

Events	31-365 days SECURITY (N=302)		0-365 days SECURITY (N=305)	
	n	%	n	%
Cardiac	57	18.9	74	24.3
MI	5	1.7	7	2.3
Arrhythmia	6	2.0	10	3.3
Angina	6	2.0	10	3.3
Congestive Heart Failure (CHF)	10	3.3	15	4.9
Coronary Artery Disease (CAD)	30	9.9	32	10.5
Procedural Complication	0	0.0	109	35.74
Hypotension	0	0.0	86	28.20
Arrhythmia	0	0.0	7	2.30
Vasospasm	0	0.0	3	0.98
Dissection	0	0.0	10	3.28
In-stent Thrombosis	0	0.0	1	0.33
Emergent CEA	0	0.0	1	0.33
Emergent Intervention -other	0	0.0	1	0.33
Access Site Complication Requiring Repair / Transfusion	0	0	8	2.62
Vascular	42	13.9	45	14.7
Hemodynamic	25	8.3	36	11.8
Bleeding	4	1.3	10	3.3
Requiring transfusion	1	0.3	2	0.7
GI Bleeding	3	1.0	8	2.6
Blood Dyscrasia	9	3.0	11	3.6
Respiratory	15	5.0	20	6.6
Gastrointestinal	8	2.6	26	8.5
Genitourinary	8	2.6	11	3.6
Infection	6	2.0	8	2.6
Metabolic	14	4.6	25	8.2
Musculoskeletal	19	6.3	51	16.7
Miscellaneous <sup>5</sup>	4	1.3	5	1.6

**Table 4: Cause of Death (< 30 days, 31-365 days)**

Cause of Death	0-30 Days		31 - 365 days	
	n	%	n	%
Stroke (neurological)	3	0.98	3	0.99
Cardiac	0	0.00	10	3.31
Cancer	0	0.00	4	1.32
Renal Failure	0	0.00	3	0.99
Respiratory	0	0.00	1	0.33
Diabetes	0	0.00	1	0.33
Device related deaths	0	0.00	0	0.00
Accidental	0	0.00	1	0.33

## 6.2 POTENTIAL ADVERSE EFFECTS

As reported in the literature, the following adverse events are potentially associated with carotid stents and embolic protection systems:

- Abrupt closure

<sup>5</sup> Adenocarcinoma, aortic aneurysm repair, aortic valve replacement and malignant hepatic neoplasm

- 
- Allergic reactions
  - Aneurysm
  - Angina/Coronary ischemia
  - Ateriovenous Fistula
  - Bacteremia or septicemia
  - Bleeding from anticoagulant or antiplatelet medications
  - Bradycardia/arrhythmia
  - Cerebral edema
  - Cerebral hemorrhage
  - Congestive Heart Failure
  - Death
  - Drug reactions
  - Embolism (including air and device)
  - Emergent or urgent Endarterectomy
  - Fever
  - Filter thrombosis/occlusion
  - Fluid overload
  - Groin hematoma, with or without surgical repair
  - Hemorrhage or hematoma
  - Hemorrhagic stroke
  - Headache
  - Hypotension
  - Hyperperfusion syndrome
  - Hypertension
  - Infection/sepsis
  - Ischemia/infarction of tissue/organ
  - Myocardial Infarction
  - Other conduction disturbances
  - Pain and tenderness
  - Pain, infection, or discomfort at the access site
  - Pseudoaneurysm
  - Renal failure/insufficiency
  - Restenosis of the stented artery
  - Seizure
  - Stent deformation, collapse, fracture, movement of stent, possibly requiring emergency surgery
  - Stent/filter entanglement/damage
  - Stroke or other neurological complications
  - Thromboembolic episodes
  - Thrombophlebitis
  - Total occlusion of the artery
  - Transient ischemic attacks (TIAs)
  - Vascular access complications (e.g. loss of pulse, femoral artery pseudoaneurysm and infection)
  - Ventricular fibrillation
  - Vessel dissection, rupture, or perforation
  - Vessel thrombosis (partial blockage)
  - Unstable angina pectoris

Any adverse event occurring involving this device should be reported immediately to Abbott Vascular Devices, Customer Service: 1 (800) 222-6883.

## 7.0 SYNOPSIS OF CLINICAL STUDY

The SECuRITY Registry Trial was a prospective, multicenter, non-randomized safety and efficacy study of an embolic protection device and a carotid artery stent in 305 pivotal patients and 93 lead-in patients with carotid artery disease conducted at 30 sites. The primary endpoint was the incidence of Major Adverse Events (MAEs), defined as death, stroke or myocardial infarction (Q-wave and non Q-wave) at 30-days post-

procedure for the Emboshield® and MAE (death, stroke or MI) at 30 days post-procedure and the incidence of ipsilateral stroke at one year for the Xact® Stent. Secondary endpoints were the incidence of vascular complications other than MAEs at 30 days, and restenosis and/or target lesion revascularization (TLR) at 6 months and one year post-procedure.

#### Study Objective

The primary objective of the study was to evaluate the safety and efficacy of the Xact® Carotid Stent System and the Emboshield® Embolic Protection System in treating carotid stenosis in patients at high risk for carotid endarterectomy ( $\geq 50\%$  stenosis for symptomatic patients by ultrasound or angiography or  $\geq 80\%$  for asymptomatic patients by ultrasound or angiography).

#### Investigational Devices

The investigational devices used over the duration of the SECURITY Registry Trial consisted of the Rapid Exchange (RX) and Over the Wire (OTW) versions of the Xact® Carotid Stent System and the RX and OTW Emboshield® Embolic Protection System.

The Xact® Carotid Stent System is comprised of a self expanding, nitinol stent that is specifically designed for use in carotid interventional procedures and a delivery system. Table 5 below provides an outline of the SECURITY Registry endpoints.

The Emboshield® system is comprised of a Filtration Element, a RX BareWire™ (guide wire), a Delivery Catheter and a Retrieval Catheter. The Emboshield® system is a temporary percutaneous, transluminal intra-arterial filtration system, which is placed distal to the target lesion. The Filtration Element is designed to appose the vessel wall distal to the target lesion in order to capture potential emboli thereby reducing the chance of distal embolization while maintaining blood flow during carotid angioplasty and stent procedures. The filtration element and retrieval catheter are removed from the patient upon completion of the procedure.

**Table 5: Study Endpoints**

Endpoint	Definition
Primary Endpoint	Incidence of Major Adverse Events (MAEs), defined as death, stroke or myocardial infarction (Q-wave and non Q-wave) at 30-days post-procedure for the Emboshield® and MAE (death, stroke or MI) at 30 days post-procedure and the incidence of ipsilateral stroke at one year for the Xact® Stent.
Secondary Endpoints	Definition
Safety	Incidence of vascular complications other than MAE at one month.
Acute Success	<b>Lesion success:</b> defined as $< 50\%$ residual stenosis of the target lesion using the Xact® stent and Emboshield® filter. <b>Device success:</b> Xact® Stent: $< 50\%$ residual stenosis in the target lesion. Emboshield®: Deployment and retrieval of the device during the procedure, in the absence of angiographic distal embolization.
Procedure success	Defined as $< 50\%$ residual stenosis of the target lesion using any method, and the absence of major adverse events at 30 days.
Long Term Success	<b>Restenosis:</b> defined as a narrowing $> 50\%$ at 6 and 12 months post-procedure, as determined by ultrasound. <b>Revascularization:</b> target lesion revascularization associated with a narrowing of $> 80\%$ within 12 months post procedure.

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## 7.1 STATISTICAL METHODS

The proportion of patients experiencing a primary endpoint adverse event in the SECURITY Registry was compared to a weighted historical control (WHC) rate based on a review of outcome assessments for endarterectomy published in peer reviewed literature. It was established that the one-year control rate for patients having high-risk co-morbidities was 14% and the one-year control rate for patient with anatomic risk factors was 11%. The WHC rate for this trial was then computed by weighting these rates by the actual proportion of patients in the study with co-morbidities versus anatomic risk factors.

Patients with at least one high-risk co-morbidity:  $266/303 = 87.8\%$

Patients with anatomic risk factors only:  $37/303 = 12.2\%$

$WHC = (87.8\% \times 14\%) + (12.2\% \times 11\%) = 13.6\%$

All patients who met eligibility requirements, and who were available for clinical follow-up, were included in the denominator. Two (2) patients had neither high-risk co-morbidities nor anatomic risk factors and were excluded from the calculation of the weighted historic control.

The analysis and subsequent interpretation of the results from this study are based on inferential statistics. The test statistic used for this analysis was the Clopper-Pearson method for calculating 95% binomial confidence intervals, based on the observed primary composite endpoint failure rate. If the upper bound of the 95% binomial confidence interval was found to be less than the WHC plus the margin of clinical equivalence, the null hypothesis would be rejected and non-inferiority of the Xact® stent to CEA would be demonstrated.

The SECURITY protocol required regular patient follow-up by the treating physician and follow-up neurological assessments by a neurologist. Core laboratories provided independent assessments for the angiographic, ultrasound, ECG, and pathologic evaluation of captured debris (Emboshield® only). Medical monitors reviewed all safety data to ensure appropriate reporting of adverse events. A Clinical Adjudication Committee adjudicated suspected primary endpoint events. A Data Safety Monitoring Board monitored adverse events to ensure patient safety.

### Eligibility Criteria Summary

Eligible patients were male and female adults with a lesion in the internal carotid artery or internal carotid artery extending into the common carotid artery who were at high risk for CEA.

All patients had to meet the following inclusion criteria to be considered for the study:

The patient had a carotid artery stenosis ( $\geq 50\%$  for symptomatic patients or  $\geq 80\%$  for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery

Patient was  $\geq 18$  years of age

Patient had a lesion located in the internal carotid artery

Target Internal Carotid Artery (ICA) vessel diameter was visually estimated to be  $\geq 4.0$  mm and  $\leq 9.0$  mm for Xact® stent treatment segment and to be  $\geq 3.5$  mm and  $\leq 6.0$  mm for the Emboshield®

Anticipated life expectancy of the patient was at least one year

The patient (or their legal guardian) understood the nature of the procedure and provided written informed consent

Patient was willing to comply with the protocol requirements and to return to the treatment center for all required clinical evaluations

Patient had no childbearing potential or a negative pregnancy test within 5 days of the study procedure

Each patient had to fulfill at least one (1) of the anatomical risk factors or co-morbid risk factors listed below to be inclusion in the study:

### Anatomic Risk Factors

Previous radiation treatment to the neck or radical neck dissection

Target lesion was at or above the second vertebral body C2 (level of jaw)

Inability to extend the head due to cervical arthritis or other cervical disorders

Tracheostomy or tracheal stoma  
 Laryngectomy  
 Contralateral laryngeal nerve palsy  
 Severe tandem lesions

**Co-morbid Risk Factors**

Previous carotid endarterectomy with significant restenosis (as defined above for symptomatic or asymptomatic patients)  
 Total occlusion of the contralateral carotid artery  
 Left ventricular ejection fraction < 35%  
 Congestive Heart Failure New York Heart Association (NYHA) Functional Class III or higher  
 Dialysis dependent renal failure  
 Canadian Cardiovascular Society Angina Classification III or higher or unstable angina  
 Requires simultaneous or staged coronary artery bypass surgery, cardiac valve surgery, peripheral vascular surgery, or abdominal aortic aneurysm repair within 60 days  
 > 80 years of age  
 Myocardial infarction within previous 6 weeks  
 Abnormal stress test. Treadmill, thallium or dobutamine echo were acceptable. The stress tests had to be sufficiently abnormal to place the patient at an increased risk for CEA  
 Severe pulmonary disease, including at least one of the following: requirement chronic O2 therapy, resting PO2 ≤ 60 mm Hg, Hematocrit ≥ 50%, FEV1 or DLCO ≤ 50% of normal

Description of Patients Evaluated

Table 6 summarizes the patient follow-up and includes one patient that died three hundred seventy four (374) days post index procedure.

**Table 6: SECURITY Patient Follow-up**

	30-days	6-months	12-months
Patients Enrolled	305		
Cumulative Death	3	13	26
Cumulative Withdrawal or Loss-to-Follow-up	10	26	36
Patients Evaluable	302	292	279
Patients Evaluated	292	266	243
Follow-up Rate (%)	96.7	91.1	87.1

Baseline demographics and lesion characteristics for the SECURITY Registry Trial are presented in Table 7.

**Table 7: Baseline Demographics**

Demographic	SECURITY Trial
<b>Age</b>	
Mean ± SD	74.5 ± 9.1
Range (min, max)	48.0, 92.2
Age > 80 years	33.8% (103/305)
<b>Gender</b>	
Male	63.6% (194/305)
Females	36.4% (111/305)
<b>Medical History</b>	
Diabetes	30.8% (94/305)
Hypertension requiring treatment	86.6% (264/305)

Demographic	SECURITY Trial
Hyperlipidemia	73.8% (225/305)
Current Smoker	72.5% (221/305)
<b>Number of Symptomatic Patients</b> (TIA/stroke within 180 days)	21% (64/305)
<b>Baseline Lesion &amp; Vessel Characteristics</b>	
Eccentric	29.0% (87/300)
Concentric	71.0% (213/300)
Calcified	21.0% (63/300)
Ulcerated	23.0% (69/300)
<b>Lesion Length (mm)</b>	
Mean $\pm$ SD	15.0 $\pm$ 6.5
Range (min, max)	2.0, 46.8
<b>Minimum Lumen Diameter (MLD, mm)</b>	
Mean $\pm$ SD	4.8 $\pm$ 0.9 (n=299)
Range (min, max)	0.8, 9.5
<b>Percent Diameter Stenosis (%DS)</b>	
Mean $\pm$ SD	73.2 $\pm$ 17.3 (n=299)
Range (min, max)	-160, 93.2
<b>High-Risk Inclusion Criteria</b>	
<b>Anatomic Risk Factors</b>	
Previous Radiation Treatment to Neck or Radical Neck Dissection	5.9% (18/305)
Target Lesion At or Above Second Vertebral Body C2	9.2% (28/305)
Inability to Extend the Head Due to Cervical Arthritis or Other Cervical Disorders	3.0% (9/305)
Tracheostomy or Tracheal Stoma	0.0% (0/305)
Laryngectomy	0.3% (1/305)
Contralateral Laryngeal Nerve Palsy	0.0% (0/305)
Severe Tandem Lesions	1.3% (4/305)
<b>Co-Morbid Risk Factors</b>	
Previous Carotid Endarterectomy with Significant Restenosis	21.0% (64/305)
Total occlusion of the Contralateral Carotid Artery	8.9% (27/305)
Left Ventricular Ejection Fraction <35%	79.9% (24/305)
Congestive Heart Failure NYHA III or Higher	6.2% (19/305)
Dialysis Dependent Renal Failure	1.6% (5/305)
CCSAC III or Higher or Unstable Angina	7.5% (23/305)
Requires Simultaneous or Staged CABG, Cardiac Valve Surgery, Peripheral Vascular Surgery, or Abdominal Aortic Aneurysm Repair Within 60 Days	7.2% (22/305)
>80 Years of Age	33.8% (103/305)
MI Within Previous 6 Weeks	0.7% (2/305)
Abnormal Stress Test	12.1% (37/305)
Severe Pulmonary Disease	2.0% (6/305)

## 7.2 RESULTS

At 30 days following the study procedure, 92.5% of the treated patients were free of major adverse events (MAEs), defined as death, stroke or myocardial infarction. The primary endpoint of the study was a composite rate of the 30-day MAEs and ipsilateral strokes at one year. The composite rate of occurrence for the primary endpoint measure at 12 months was 8.5%.

Acute success in effectively treating the target lesion was demonstrated in 96.7% (295/305) of the patients undergoing the study procedure. Device success was also achieved in a majority of the study procedures for both study devices: 94.1% (287/305) for the Xact<sup>®</sup> stent and 96.7% (295/305) for the Emboshield<sup>®</sup> Embolic Protection System.

Overall procedural success was demonstrated in 269 patients (88.2%), as measured by a residual stenosis of < 50% at the completion of the procedure and the absence of major adverse events (MAE; Stroke, Death,



or MI) at 30 days. Five (5) patients (1.6%, 5/305), experienced a vascular complication that required treatment with additional therapeutic measures, including aspiration of a stagnate column of blood prior to filter retrieval, placement of a second stent, application of a pressure dressing to the access site and surgical drainage for a groin abscess.

Change to minimum lumen diameter (MLD) was calculated for 299 patients where the MLD measured was the section (segment) of the carotid considered for stenting. The average change was 2.3mm and the average percent change in lumen diameter was -55.5%.

At 12 months, long-term durability of the procedure was also demonstrated by 99.3% (0.7%, 2/305) of the treated patients being free from repeat revascularization. Additionally, at 6 months and 12 months post-procedure, restenosis was demonstrated in a small percentage of the patient population, 4.9% and 4.1%, respectively.

In the SECURITY trial the median number of days-to-discharge was 1.7. The longest hospital stay post-stenting in each study was 16 days. Approximately, 70% of patients in the SECURITY Trial remained in the hospital for 1 day following the carotid stenting procedure. Additionally, 6% of patients stayed 5 or more days, generally for the treatment of a co-morbid condition.

The primary objective of the SECURITY trial was met. The upper bound of the 95% one-sided binomial confidence interval was found to be less than the WHC plus the margin of clinical equivalence, demonstrating that the carotid stenting with the Xact® stent is non-inferior to carotid endarterectomy.

The clinical results of this study indicate that the Xact® Carotid Stent System, when used in conjunction with the Emboshield® Embolic Protection System, provides a safe, effective and durable method for the treatment of carotid stenosis in patients at high-risk for carotid endarterectomy.

**Table 8: Summary of Safety Measures in the SECURITY Trial**

Events	≤ 30 Days SECURITY (N=305)	
	n	%
30 Day Primary Endpoint (Death, Stroke and MI)	23	7.5 %
Death	3	0.98 %
Stroke-Related	3	0.98 %
Not Stroke-Related	0	0 %
All Strokes	21	6.89 %
Major	8	2.62 %
Ipsilateral Stroke	7	2.30 %
Non-ipsilateral Stroke	1 <sup>6</sup>	0.33 %
Minor	13	4.26 %
Ipsilateral Stroke	12	3.93 %
Non-ipsilateral Stroke	1 <sup>7</sup>	0.33 %
Non-Stroke Neurological	25	8.20 %
Cardiac	15	4.92 %
MI	2	0.66 %
Arrhythmia	4	1.31 %
Angina	4	1.31 %
Congestive Heart Failure (CHF)	3	0.98 %
Coronary Artery Disease (CAD)	2	0.66 %
Procedural Complication	109	35.74 %
Hypotension	86	28.20 %
Arrhythmia	7	2.30 %
Vasospasm	3	0.98 %
Dissection	10	3.28 %
In-stent Thrombosis	1	0.33 %
Emergent CEA	1	0.33 %
Emergent Intervention -other	1	0.33 %
Access Site Complication		

<sup>6</sup> Stroke adjudicated as contralateral

<sup>7</sup> Stroke adjudicated as bilateral

Events	≤ 30 Days SECURITY (N=305)	
	n	%
Requiring Repair / Transfusion	8	2.62 %
Vascular	3	0.98 %
Hemodynamic	11 <sup>a</sup>	3.61 %
Bleeding	6	1.97 %
Requiring transfusion	1	0.33 %
GI Bleeding	5	1.64 %
Blood Dyscrasia	2	0.66 %
Respiratory	5	1.64 %
Gastrointestinal	18	5.90 %
Genitourinary	3	0.98 %
Infection	2	0.66 %
Metabolic	11	3.61 %
Musculoskeletal	32	10.49 %
Miscellaneous <sup>a</sup>	1	0.33 %

**Table 9: Summary of Efficacy Measures in the SECURITY Trial**

Efficacy Measures	%	95% CI	X/n
<b>One Year Primary Endpoint</b> (Stroke, Death, MI within 30 days plus ipsilateral stroke 31-365 days)	8.5	(-, 0.116)	(26/305)
<b>Lesion Success</b> (< 50% stenosis using the Xact® stent and Emboshield® filter)	96.7%	(0.941, 0.984)	(295/305)
<b>Device Success - Xact® Stent</b> (< 50% residual stenosis, successful delivery of the stent)	94.1%	(0.908, 0.965)	(287/305)
<b>Device Success - Embolic Protection Device</b> (Successful deployment/retrieval of the filter, absence of angiographic distal embolization)	96.7%	(0.941, 0.984)	(295/305)
<b>Procedural Success</b> (< 50% stenosis using any method and freedom from MAE at 30 days)	88.2%	(0.840, 0.916)	(269/305)
<b>Long Term Success</b> (absence of Ipsilateral stroke at 365 days post-procedure [0-365 days] )	92.2%	(0.889, 0.952)	(282/305)
<b>Restenosis</b> (≥ 50% stenosis as measured by ultrasound)*			
At 6 Months post-procedure	4.9%	(0.020, 0.067)	(12/246)*
At 12 Months post-procedure	4.1%	(0.014, 0.055)	(9/221)*
<b>Target Lesion Revascularization</b> (Surgical/percutaneous revascularization involving the target lesion within 365 days)	0.65%	(0.000, 0.018)	(2/305)
<b>Total Vascular Complications</b>	1.6%	(0.005, 0.038)	(5/305)

\*At the end of the one year follow-up period only two subjects had a clinically indicated need for revascularization.

<sup>a</sup> Includes hypotension and hypertension not associated with the procedure.

<sup>a</sup> Aortic aneurysm repair

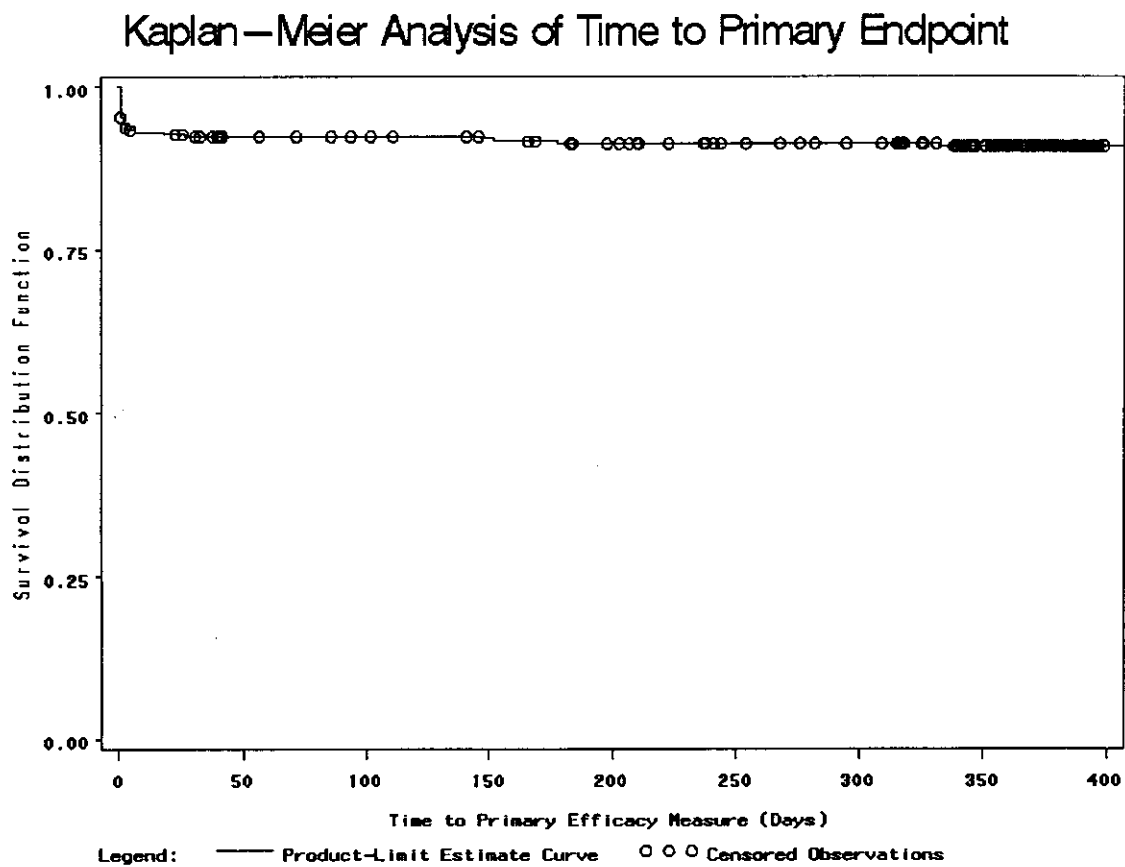
**Table 10: Improvement in Target Lesion Lumen Diameter**

	Pre-Procedure to Post-Procedure Change (n=295**)		
	Change Mean	S.D.	95% CI
In Lesion MLD* (mm)	2.3mm	0.7mm	(2.3, 2.4)
In Lesion Diameter Stenosis (%)	-55.5%	15.6%	(-57.3, -53.7)

\*Minimum Lumen Diameter of the section (segment) of the carotid considered for stenting

\*\*Number of patients for which pre- and post- angiographic data was available.

**Figure 4: Freedom from Composite Endpoint of Stroke, Death and MI (0-365 days)**



Months after Index Procedure	0	1	3	6	12
Days after Index Procedure	0	30	90	180	365
Number at Risk	305	276	264	253	157
Number Censored	0	6	18	26	121
Number of Events	0	23	23	26	27
Percent Event Free	100%	92.4%	92.4%	91.4%	91.0%
One-Sided Lower 95% CI	100%	89.9%	89.9%	88.6%	87.4%

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## 8.0 CLINICIAN USE INFORMATION

**Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.**

**Warning:** The Xact® Carotid Stent System is intended for one time use only. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and risk of cross contamination.

**Warning:** Do not use the product after the Use by Date specified on the package.

### 8.1 MATERIALS REQUIRED

Confirm the compatibility of the Xact® Carotid Stent System with the interventional devices before actual use.

6F introducer sheath or 8F guiding catheter compatible with the vascular anatomy. Minimum guiding catheter/sheath size inner diameter (I.D.) 0.088"/ 2.4 mm

0.096" (2.44 mm) Rotating Hemostatic Valve (RHV) (optional)

Emboshield® Embolic Protection System and RX BareWire™

Balloon dilation catheter (optional)

1,000 u / 500 cc heparinized normal saline (sterile)

3ml luer-lock syringe

### 8.2 PERIPROCEDURAL CARE

During the SECURITY trial, when possible, aspirin 325 mg once a day, and clopidogrel 75 mg once a day were started at least 72 hours prior to the procedure. Administration of heparin was recommended immediately after sheath placement. At a minimum, prior to any intervention to the carotid artery, all patients received 5,000 units heparin IV/IA or an equivalent dose sufficient to achieve a target ACT of 200 to 250 seconds. After the procedure, aspirin 325 mg once a day was continued permanently and clopidogrel 75 mg daily for four weeks.

### 8.3 PRE-PROCEDURE

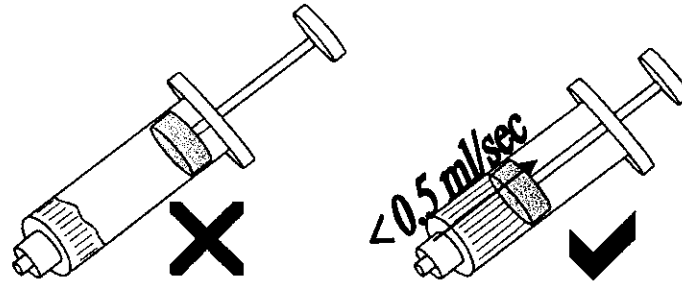
Refer to Section 8.2 of these instructions for the suggested pre-procedure pharmacological treatment regimen. The placement of the stent in a stenotic or obstructed carotid artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present, do not proceed with stent deployment. Access vessels must be sufficiently patent or sufficiently recanalized to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

#### Using Contrast Media

During the insertion of rapid exchange catheters through guide catheters or sheaths careful handling is required to ensure that air is not drawn into the access device. It is therefore recommended that flushing of contrast media (or other fluids) is performed before or after insertion of the catheter, but not while the catheter is within the access device.

In the case where a contrast media injection must be performed with the catheter in place it is essential to ensure that no air is present within the access device prior to injection. This risk will be minimized by following the instructions of slow catheter insertion and good hemostasis valve control.

If aspiration is to be performed prior to contrast media injection it should be performed slowly and steadily at a rate of not more than 0.5ml (0.5cc) per second until it can be visually confirmed that no further air is entering the aspiration syringe.



#### 8.4 STENT SIZING

See Table 11 and Table 12 for stent sizes and diameters and recommended reference vessel diameters for straight and tapered stents.

The Xact® Carotid Stent System is provided in a range of lengths, diameters and configurations. Care should be taken to select the most appropriately sized Stent. The device range is specified in Table 1. The Xact® Stent undergoes > 8% foreshortening during deployment.

**WARNING: The Xact® Carotid Stent System is contraindicated for use with lesions in the ostium of the common carotid artery.**

Table 11: Stent Sizing (Straight Stent)

Reference Vessel Size	Unconstrained Stent Diameter
>5.5 – 6.4mm	7.0 mm
>6.4 – 7.3mm	8.0 mm
>7.3 – 8.2mm	9.0 mm
>8.2 – 9.1mm	10.0 mm

Table 12: Stent Sizing (Tapered Stent)

Lumen Diameter Range for the Proximal End	Lumen Diameter Range for the Distal End	Tapered Unconstrained Stent Diameter
>6.4 – 7.3 mm	4.8 – 5.5mm	8.0-6.0 mm
>7.3 – 8.2mm	>5.5 – 6.4mm	9.0-7.0 mm
>8.2 – 9.1mm	>6.4 – 7.3mm	10.0-8.0 mm

## 8.5 DELIVERY SYSTEM PREPARATION

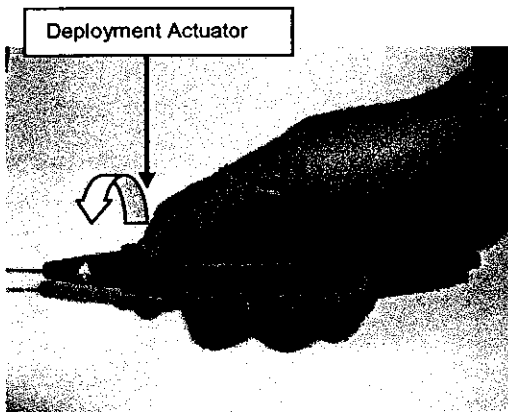
- Remove the pouched device from the box.
- Examine the pouch for any signs of damage to the sterile barrier.

If it is suspected that the sterile barrier has been compromised, do not use the device and return it to the manufacturer.

**CAUTION:** Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and / or function of the device may be impaired.

The device must only be flushed using the 3-ml syringe and flushing tip provided.

- Peel open the pouch and remove the device from the pouch, maintaining device sterility.
- Remove the device from its protection hoop by pulling the device out by the Handle. Examine the device for any damage. If any damage is observed, do not use the device and return it to manufacturer.
- Attach the 3-ml syringe, filled with sterile heparinized saline solution, to the Flushing Tip and flush via the device tip until saline exits both between the tip and the catheter shaft (Figure 1, No. 5 and 3) and also at the RX Guide Wire Exit Port (Figure 1, No. 10).
- Examine the distal end of the device to ensure that no part of the stent is exposed. Do not use the device if any portion of the stent is exposed, and return it to the manufacturer.
- If a gap between the tip and the Outer Sheath exists, rotate the Deployment Actuator in an anti-clockwise direction (opposite direction to arrow marking on handle) until the gap is closed. (See Figure 5)



- Hold the handle as shown in Figure 5
- Rotate the Deployment Actuator in the opposite direction to the arrow on the handle.

**Note** Do not rotate the Deployment Actuator and the Handle together.

Figure 5: Retracting the Tip

## 8.6 INTRODUCTION OF THE STENT DELIVERY SYSTEM

**Note:** After percutaneous access is obtained, heparin should be used to maintain an ACT greater than 250 seconds.

- Access the treatment site using the appropriate accessory equipment compatible with the Xact® 5.7 Fr Delivery System.

The outside diameter of the Outer Sheath is 5.7Fr. The minimum guiding catheter/sheath size inner diameter (I.D.) required is 0.088"/ 2.4 mm

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**Do not use a prepared Xact® Carotid Stent System if the stent is not fully constrained within the Delivery System.**

- Deploy the Emboshield® System. Other percutaneous interventional devices should be passed over the RX BareWire™.
- If required, pre-dilate the lesion using standard angioplasty techniques over the RX BareWire™.
- Advance the Xact® Carotid Stent System over the RX BareWire™. The Deployment Actuator should not be rotated before the constrained stent (within the Stent Delivery System) has been positioned at its intended deployment location. If, after preparation, a gap between the catheter tip and the outer sheath exists, rotate the Deployment Actuator in an anti-clockwise direction until the gap is closed.

**Maintain a snug seal between the device and the hemostasis Tuohy/Borst valve during insertion. Failure to observe this may result in air being drawn into the access device through the hemostasis/Tuohy Borst valve. Device insertion should be performed slowly to minimize the risk of air entrainment.**

**Do not advance any component of the Xact® Carotid Stent System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.**

## **8.7 STENT DEPLOYMENT**

- Advance the Stent Delivery System until the radiopaque markers are appropriately positioned proximal and distal to the target lesion.

**The Deployment Actuator should not be rotated during introduction of the Stent Delivery System.**

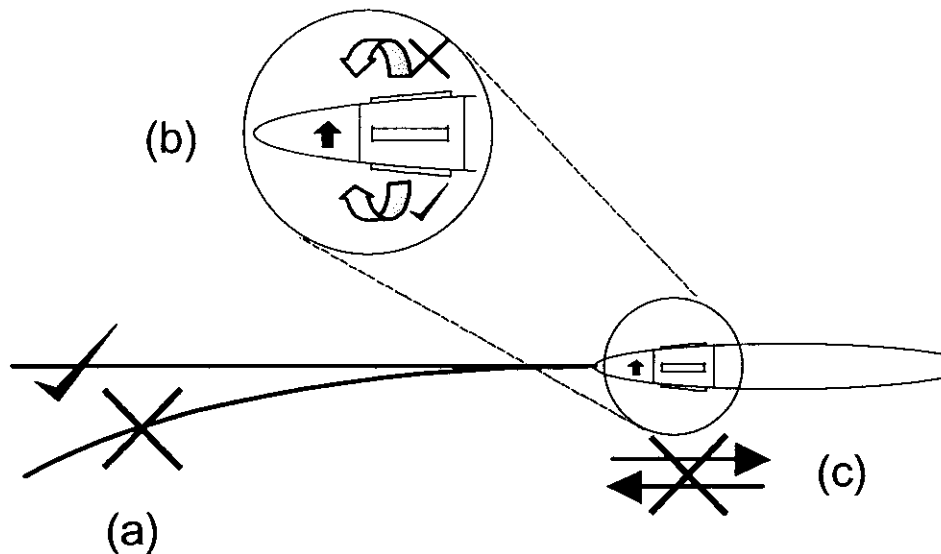
- Ensure that the hemostasis valve is tightened on the Stabilizer (Figure 1, No. 11). Secure the Handle in one hand. Ensure that the portion of the catheter shaft that remains outside the sheath/guide catheter is straight (Figure 6-a). The direction of rotation, which will initiate stent deployment, is shown by the arrow on the Handle. Slowly rotate the Deployment Actuator of the Handle in a clockwise direction (Figure 6-b). This rotation will initiate stent deployment.

**If a filter element embolic protection system is used, allow for and maintain adequate distance between the filter and the stent delivery system or deployed stent to avoid potential entanglement. During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. The stent delivery system should not contact the Filtration Element.**

- The Delivery System may be repositioned prior to the stent making contact with the vessel wall. The hemostasis valve must be opened prior to repositioning the stent. The hemostasis valve should be re-tightened on the Stabilizer before stent deployment is continued.

**Do not attempt to reposition the Delivery System after the stent has made contact with the vessel wall.**

- Deployment is complete when the entire stent is released and in contact with the vessel wall.
- Once the stent has made contact with the vessel wall, do not move the Delivery System until the stent has been fully deployed (Figure 6-c).



**Figure 6: Stent Deployment**

**CAUTION:** When more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent for placement of the distal stent, and reduces the chance of dislodging stents that have already been placed.

**CAUTION:** If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum (approximately 5mm). In no instance, should more than 2 stents ever overlap.

**CAUTION:** Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

**WARNING:** Overstretching of the artery may result in rupture and life-threatening bleeding.

## 8.8 POST-DEPLOYMENT STENT DILATATION

- Open the hemostasis valve and withdraw the Delivery System under fluoroscopic observation.

If any significant resistance is met during Delivery System withdrawal, the cause of any resistance should be determined via fluoroscopy and remedial action taken.

- Using fluoroscopy, assess the stent deployment.
- The stent may be post dilated if required.

## 8.9 POST STENT PLACEMENT

Once final angiography confirms a satisfactory result, the Emboshield® System should be retrieved as per the Instructions for Use. All other ancillary devices should be removed and, if required, the puncture site closed.



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## **9.0 PATIENT INFORMATION**

A Patient Guide which includes information on carotid artery disease and the carotid stent implant procedure using embolic protection is available from Abbott Vascular Devices upon request. Please contact Customer Service at 1 (800) 222-6883 to obtain copies.

## **10.0 HOW SUPPLIED**

**Sterile:** This device is sterilized by Ethylene Oxide. Non-pyrogenic.

**Contents:** Each Xact® Carotid Stent System contains an Xact® stent premounted on a delivery system, a 3 ml Syringe and a Flushing Tip

**Storage:** Store in a dry, cool place.

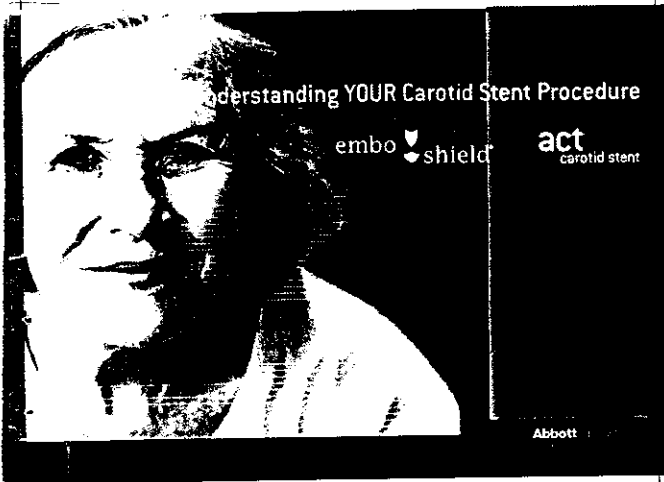
### **Disclaimer of Warranties**

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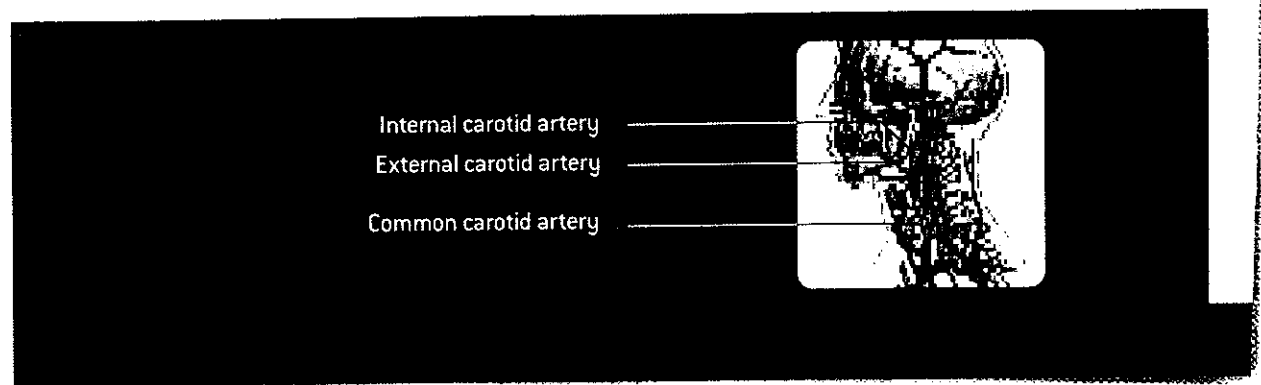


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# Carotid Anatomy and Your Brain

You have two carotid arteries – one on each side of your neck, just next to your windpipe. These arteries supply blood to the large front section of your brain, which is responsible for thinking, speech, personality and sensory and motor functions. You also have two smaller arteries, the vertebral arteries, that run up your spine and supply blood to your brainstem and cerebellum.



## Carotid Artery Disease and Strokes

Just like the arteries in your heart, the carotid arteries can narrow and develop blockages. This disease process is known as atherosclerosis, and the blockages, made of fat and cholesterol deposits, are called plaque. The disease can cause a decrease in blood flow to the brain, ultimately leading to a stroke.

The following factors may increase your chance of atherosclerosis and, as a result, stroke:

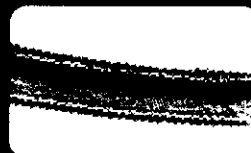
- Smoking
- High blood pressure
- High fat/high cholesterol diet
- Family history of stroke
- Race/ethnicity
- Prior history of stroke
- Diabetes
- Age
- Being overweight

A stroke is similar to a heart attack and occurs when the brain is deprived of oxygen rich blood. This can occur in one of three ways:

When an artery becomes narrowed

When a piece of plaque breaks off and travels to the smaller arteries of the brain

When a clot forms in the narrowed artery



# Diagnosis of Carotid Artery Disease

There are not necessarily warning signs for carotid artery disease, but there are warning signs of an impending stroke. Many times a stroke is preceded by a Transient Ischemic Attack (TIA or "mini-stroke"). A TIA is a temporary (lasting a few minutes to a few hours) episode of any of the following events:

- Blurred or loss of vision in one or both eyes
- Weakness and/or numbness of your arm, leg or face on one side of your body
- Slurring of speech, difficulty talking or understanding what others are saying
- Loss of coordination, dizziness or confusion
- Trouble swallowing
- Headache

NOTE: A TIA is a medical emergency. Immediate treatment may save your life or increase your chance of a full recovery.

Sometimes a patient may not know that he or she has diseased carotid arteries. In these cases, it is important that the carotid arteries are routinely assessed as part of a regularly scheduled physical exam. Initially, the physician will listen to the carotid arteries with a stethoscope. If an abnormal whooshing sound, called a bruit (BR00-ee) is heard, disease may be present. Bruits, however, are not always present when a blockage is present, and a bruit may be heard in even the most minor of narrowings.

If a sign or symptom, as described on the previous page exists, your doctor will prescribe one or more of the following diagnostic tests:

## Carotid Duplex Ultrasound

- An imaging procedure using high frequency sound waves to view the carotid arteries and determine the presence of disease. This procedure is non-invasive (performed outside of the body) and is generally conducted on anyone with a previous history of atherosclerosis or over the age of 60.

## Carotid Angiography [Carotid Angiogram, Angio or Arteriogram]

- An invasive imaging procedure involving the insertion of a small catheter into a blood vessel, generally in the leg. The catheter is guided to the carotid arteries with the aid of a special X-ray machine, and X-ray dye is injected through the catheter so that images of the carotid arteries may be recorded.

## Magnetic Resonance Angiography [MRA]

- Non-invasive carotid angiography performed using Magnetic Resonance Imaging (MRI) instead of X-ray. Contrast media, specific to MRI, is injected through an IV for visualization of the carotid arteries.

## Computerized Tomography [Cat Scan, CT]

- A non-invasive imaging technique that may be used if there is a possibility that a stroke has already occurred. X-ray dye may be injected through an IV line to reveal areas of the brain that have been damaged by a stroke.

# Treatment Options

## Lifestyle Modification

- Quit smoking and using tobacco products
- Control high blood pressure and diabetes
- Have regular check-ups with your doctor
- Maintain a diet of foods low in saturated fats and cholesterol
- Monitor and control your lipids (good vs. bad cholesterol levels)
- Achieve and maintain a desirable weight, including regular exercise
- Properly control other physical ailments, such as atrial fibrillation and heart disease

## Medication

- Blood thinners (anti-coagulants), such as aspirin, Coumadin™ (warfarin) and/or Plavix™, will be prescribed to reduce the risk of blood clots. These medications will require regular blood work to ensure proper dosage.

## Procedures

- Carotid Endarterectomy (CEA):
  - This surgical treatment is performed while the patient is under general anesthesia. An incision is made in the side of the neck, at the location of the blockage (generally just below the jaw), and into the carotid artery. The plaque and any diseased portion of the artery is removed and the artery is sewn back together to allow blood flow to the brain.
- Carotid Artery Stenting (CAS):
  - This is a non-surgical procedure that is performed in a catheterization laboratory. A small puncture is made in an artery in the groin, and catheters and wires are inserted under specialized X-ray. During this procedure, balloons, stents (mesh-like tubes that act as scaffolding in the carotid artery) and small filters (to capture particles from the blockage and prevent a stroke) are placed in the carotid artery via the previously placed catheters and wires.



## During the Carotid Stent Procedure

Before you go to the hospital, your doctor will give you instructions on any medication and diet changes necessary prior to your stent procedure. Your doctor may also direct you not to eat or drink anything after midnight of the night before your procedure. You should follow these instructions carefully and ask questions if you are uncertain or concerned.

Be sure to tell your doctor in advance if you have any allergies. It is especially important that you let your doctor know if you are allergic to contrast dye, iodine or any metals.

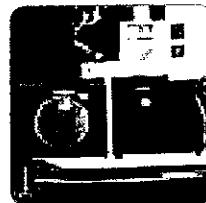
Just before your procedure (generally the morning of), you will arrive at the hospital and be registered into the system. You will change from your street clothes into a hospital gown, have an IV started and complete any remaining testing (blood work, ECG, ultrasound, etc.). Any necessary medications, such as sedatives and blood thinners, may be given via the IV or by mouth.

Once you enter the catheterization laboratory, many things will happen at once:

- Physicians, nurses and technologists will place you onto the procedure table and attach monitoring equipment to you for the stenting procedure.
- You may be given additional medication to help you relax.
- During the procedure, the room will be darkened and a large camera placed over you. The camera will rotate and move throughout the procedure.
- Just prior to placing any catheters into your groin, you will feel a small stinging sensation as your doctor numbs the area.

During the procedure, you will see, hear and feel many things:

- The doctor will use various wires and catheters to gain access to your carotid artery. These catheters will enter your body through the small incision in your groin. The catheters will travel through your body via your arteries until they reach the area to be treated. Because there are no nerve endings in your arteries, you will not be able to feel these wires and catheters moving inside you.



- As your doctor treats you, he or she will take many X-ray pictures of you using the X-ray camera and contrast dye. This contrast dye may briefly make you feel warm as it is injected.
- Once the doctor has gained access to your carotid artery, he or she will deploy a tiny filter downstream from the area that will be treated. It is possible for plaque from the diseased area to break loose and be carried downstream during the procedure. The filter, the Emboshield Embolic Protection Device, will help to catch any of that debris and prevent it from reaching your brain. For your protection, the filter will remain open in your artery throughout the procedure.
- If the disease in your artery has caused the vessel to become very narrow, your doctor may use a small balloon to open it slightly. This will help the doctor to reach the area where your stent will be placed. You may feel some pressure in your neck while the balloon is inflated.
- Your doctor will use a special catheter to place the stent in the area of your carotid that will be treated. This catheter contains the stent in a compressed, or crimped, state. The doctor will carefully align the delivery catheter and then deploy the stent. This stent, the Xact Carotid Stent, is designed to hold diseased plaque against the wall of your artery and to prevent that plaque from breaking loose and being carried into your brain.
- After the Xact stent is deployed, your doctor may use another small balloon to ensure that your artery is fully opened and any plaque is pushed against the vessel wall. You may feel a small amount of pressure in your neck as the balloon is inflated.
- When your doctor is satisfied that your artery has been treated properly, he or she will close the filter and remove it. The filter is designed to trap and contain any debris that has been dislodged during the procedure.

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You should follow your doctor's instructions throughout the procedure. You should also let him or her know if you experience any unusual sensations.

- It is important that you remain calm throughout the procedure. Try to stay as relaxed as possible and to breathe normally.
- You should carefully follow any instructions that your doctor gives you. You may be asked to speak, move your fingers or turn your head. You will also be told to hold your breath and remain very still for short periods of time. During those periods, the doctor will take highly detailed pictures of you with the X-ray camera. If you move or breathe during those pictures, they will be blurry and difficult for the doctor to read.
- You should let your doctor know immediately if you experience any unusual sensations such as pain, dizziness, numbness, tingling, or difficulty seeing, hearing, speaking or swallowing.

Once your procedure is complete, the catheter that allows access to your arteries will be removed. After it is removed, you will be placed on bed rest in the hospital. The amount of time before you are allowed to stand or move freely will depend on how the incision from the catheter insertion is closed and what medication you have been given. During this time, the doctors and nurses will carefully monitor your vital signs. As always, you should let your doctor know immediately if you experience any unusual sensations such as pain, dizziness, numbness, tingling, or difficulty seeing, hearing, speaking or swallowing.

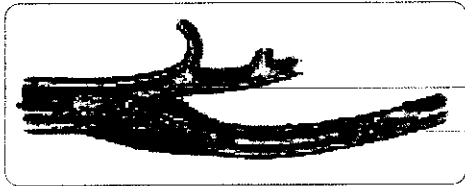
# Device Descriptions

## Xact Carotid Stent

- A stent is a small mesh-like tube made out of metal that acts as scaffolding to assist in opening blockages in the carotid artery and maintaining blood flow to the brain. The Xact Carotid Stent is made out of a metal alloy called NiTinol, which expands to a predetermined size once deployed within the body. Angioplasty balloons are used to ensure that the stent is opened properly for optimal results.

## Emboshield Embolic Protection System

- The Emboshield Embolic Protection System includes a small filter that is placed in the carotid artery, just past the blockage, before the stent is deployed. The Emboshield is used in conjunction with the Xact stent to ensure any plaque particles that are knocked loose during the procedure do not reach the brain and cause a stroke.



• Xact Stent

• Emboshield

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## Going Home

After your procedure is complete, your doctor will carefully track your recovery. When he or she feels that it is safe, you will be allowed to return home. Your doctor will give you detailed guidelines for activities, diet and medications.

**NOTE:** Because medications will be an important part of your treatment, your physician will prescribe drugs that you should take at home to help prevent clots from forming. The most commonly prescribed drugs are aspirin and blood thinners.

You should follow your doctor's instructions very carefully and ask questions if there is anything you do not understand. You may be told to limit some activities (such as driving and exercising) until your recovery has progressed further. Although you may feel better quickly, you should get plenty of rest and follow your doctor's directions regarding what to eat and drink.

It is also important to keep all follow-up appointments that are scheduled for you. Your doctor will want to follow your progress closely and will give you tests such as an ECG, ultrasound and/or blood work. These tests are designed to detect any problems that may arise, and they will help your doctor to ensure your complete recovery.



You may need to have an MRI or MRA to look at your arteries after your procedure. You can have an MRI or MRA at anytime after your stent is implanted. The Xact Carotid Stent is MRI compatible. However, let the people operating the MRI machine know that you have a stent. Please keep your stent implant card with you and present it to the people running the MRI machine so they know what type of machine to use.

The majority of patients who go home after a successful stent implantation have no further problems. If you do experience any TIA-like symptoms, discomfort, or bleeding from your puncture site, immediately contact your doctor. If your doctor is unavailable, contact your local emergency service and have them take you to the nearest hospital.

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## Contraindications, Potential Complications and Adverse Effects

It is important to know whether you are eligible for carotid stenting with the Xact and Emboshield. There are certain circumstances when carotid stenting presents too high of a risk, and you and your doctor should discuss whether carotid stenting is right for you. If you have questions about the lists below, you should discuss them with your doctor. Here are some of the reasons why carotid stenting with the Xact and Emboshield may not be right for you:

- You cannot tolerate anti-coagulants and/or anti-platelet therapies.
- The narrowed area in your carotid artery is too sharply curved for your doctor to treat you safely. Devices such as the guiding catheter/introducer sheath, RX Barewire, Emboshield delivery catheter, filtration element or retrieval catheter may not be able to reach and cross the area of your carotid artery that requires treatment. In our clinical trial, physicians were unable to successfully place the Xact and Emboshield in approximately 3.3% of patients.
- You have an allergy or hypersensitivity to nickel and/or titanium. The Xact Carotid Stent is made of a nickel-titanium alloy, and some patients may suffer dangerous reactions to these metals.
- You have an uncorrected bleeding disorder. If you have an uncorrected bleeding disorder, treatment with the Xact and Emboshield could lead to dangerous bleeding complications.
- You have arterial disease in the ostium of your common carotid artery. Disease in this area of your carotid artery should not be treated with the Xact and Emboshield.

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As with all invasive medical procedures, there are also risks to carotid stenting and angioplasty. Some of the risks may be difficult to understand, but they are nevertheless very serious. In Abbott's clinical trial with the Xact and Emboshield, 7.5% of patients suffered a stroke, heart attack [myocardial infarction], or death in the first thirty days after their procedure. In the time period between the end of the first month and the end of the first year, 1.7% of patients suffered a stroke on the same side as the treated artery. It is important that you discuss all the potential risks with your doctor and ask any questions you may have about them. The choice of your treatment is a decision that you and your doctor must make together, and you should make every effort to understand the risks you face before you select carotid stenting. Here is a list of the potential complications:

- Allergic reactions, bleeding, heart attack, stroke, TIAs and even death.
- Damage to your blood vessels.
- Problems with blood flow or blood clots (restenosis) at the area where the carotid stent was placed, including low blood pressure and high blood pressure. In Abbott's clinical trial, approximately 3.6% of patients suffered blood-pressure related problems in the month after their procedures.
- Headaches and/or fever.
- Problems with the rhythm of your heart such as a slow heartbeat, irregular heartbeat or uneven heartbeats. Approximately 4.9% of patients suffered some form of heart problem in the first month after being treated with Xact and Emboshield.
- Infection, pain or bruising of the groin area where the catheter was inserted. Approximately 2.6% of patients suffered some sort of complication with their access sites that required repair or transfusion. Less than 1% of patients suffered an infection in the first month after their procedures.

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Please carry this card at all times and show it to any medical personnel who may be treating you.

Patient Name \_\_\_\_\_  
 Date of Implant \_\_\_\_\_  
 Right Carotid \_\_\_\_\_ Left Carotid \_\_\_\_\_  
 Implanting Physician \_\_\_\_\_  
 Physician Contact Number \_\_\_\_\_  
 Hospital Name and Address \_\_\_\_\_

- Swelling or bleeding in the brain.
- Chest pains.
- Embolism (including air and device) debris (plaque, air bubbles or device components) admit in the blood stream.
- Stent deformation, collapse, fracture, movement of stent (possibly requiring emergency surgery).
- Failure of the stent structure or stability that may require repeat endovascular treatment or surgery. Less than 1% of the patients in Abbott's clinical trial required repeat treatment of the carotid artery that had been treated with Xact.
- Renal failure: failure of the kidneys to filter toxins and waste from your blood.

Some of these complications may be difficult for you to diagnose on your own. Things like unusual pain, numbness, tingling, dizziness, headaches, difficulty speaking, swallowing, breathing, seeing or hearing, changes in the temperature or color of your limbs, fevers, chills and weakness/tiredness are all cause for concern. You should immediately notify your doctor if you experience any unusual sensations or symptoms. If your doctor is unavailable, contact your local emergency service and have them take you to the nearest hospital.

The site of your incision should heal smoothly, although it may be tender to the touch for some time. If you notice any unusual bruising, bleeding, changes in temperature, discoloration or pain, you should contact your doctor immediately.

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back cover

Attach Label from Xact

Stent Implant Card  
**act**  
 Carotid Stent

Attach Label from Emboshield

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